

Remarks

Claims 1-15 and 19-25 are pending in this application. Claims 16-18 have been withdrawn. Applicants have herein canceled claims 3 and 19 and incorporated such in to claim 1. Applicants have also amended the present claims herein to delete “delivery system” and insert “gel film” therefor. This amendment is supported in the present specification, for example, at page 6, line 6. It is respectfully submitted that the amendments herein are supported by the present specification. Accordingly, entry of the amendments is respectfully requested. In view of the amendments and arguments set forth herein, reconsideration and allowance of the pending claims are respectfully requested.

Restriction Requirement

A restriction requirement and election of species was issued in the present application. At pages 7 and 8 of the Office Action, the Examiner notes Applicants earlier elections made by telephone. Applicants hereby affirm: (i) election of Group I, claims 1-15 and 19-25, in response to the Restriction Requirement; and (ii) election of a pharmaceutical agent as the active substance in claim 2; kappa carrageenan as the second film former in claims 10 and 11; and glycerin as the plasticizer in claim 11. Both elections are made without traverse.

Objection to the Specification

The Examiner objected to the word “hydrozylate” in the present application on the basis that this word is unclear. Applicants respectfully submit that one skilled in the art would readily understand what this term means and that the Examiner has

offered no basis to support the objection. Indeed, it would appear that this term, as spelled herein, is used in granted US patents. Withdrawal of the objection is respectfully requested.

35 USC § 112, Second Paragraph

The Examiner rejected claims 1-15 and 19-25 under 35 USC § 112, second paragraph, on the basis that the word “system” in the claims is indefinite. More specifically, the Examiner argues that this word implies a combination of product and process, but that no process steps are recited. Further, the Examiner argues that the word “system” in the present claims is unclear because the present claims do not recite the proximity of the claimed components with regard to time and space. The Examiner suggests that the word “system” should be replaced with the word “composition.”

Applicants respectfully submit that the word “system” is clear to one skilled in the art based upon the knowledge of one skilled in the art and the present specification. However, in order to advance prosecution, Applicants have herein amended the claims to delete the phrase “delivery system” from claims 1, 2, 4-15 and 20-25 and replace such with the phrase “gel film.”

Based upon this amendment to the claims, withdrawal of the rejection of claims 1-15 and 19-25 under 35 USC § 112, second paragraph, is respectfully requested.

35 USC § 112, Second Paragraph

At page 11 of the Office Action, the Examiner rejected claims 1-15 and 19-25 under 35 USC § 112, second paragraph, as being indefinite on the basis that the

present claims recite that the gel films are thermoreversible, but that alginates have been regarded as forming thermo-irreversible gels.

Applicants respectfully traverse this position on the basis that one skilled in the art would readily understand the presently claimed, thermoreversible, gel films in view of the knowledge existing in the field and the present specification. For example, at page 6 of the present specification, Applicants explained that the “thermoreversible film” of the invention defines a “film that has a melting temperature. As used herein the melting temperature is the temperature or temperature range over which the film softens or flows.” At page 5 of the present specification, Applicants explained that: (1) alginate is known to react and crosslink with available polyvalent cations; (2) certain alginates, such as sodium alginate, are known to form thermally irreversible gels with calcium; (3) crosslinking can adversely impact the thermoreversibility of the alginate gel film; (4) therefore, it is important that the alginate have levels of those polyvalent cations that adversely impact thermoreversibility below the point that such impair film formation and thermoreversibility. As a result, one skilled in the art would readily understand what the phrase in question means and the resulting thermoreversible gel films of the present invention. Withdrawal of the rejection is respectfully requested.

Double Patenting Rejection

The Examiner provisionally rejected claims 1-2, 5-15, 19-21 and 23-25 on the ground of obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 8-12, 17-19 and 35-37 of copending USSN 10/824,919 in view of Chapdelaine and Pearce.

Applicants will file a terminal disclaimer in response to this provisional obviousness-type double patenting rejection at such time as an indication of allowable subject matter is received.

35 USC § 103

At page 16 of the Office Action, the Examiner rejected claims 1-2, 9, 12-15 and 19-21 under 35 USC § 103 as being unpatentable over Zerbe in view of Day and Imre (“Obviousness Rejection 1”). At page 19 of the Office Action, the Examiner rejected claims 1-8, 10-11 and 22-25 under 35 USC § 103 as being unpatentable over Pearce in view of Day, Chapdelaine and Earle (“Obviousness Rejection 2”).

Applicants have herein incorporated claim 3 into claim 1. As a result, since claim 3 was not included in Obviousness Rejection 1, withdrawal of this rejection is respectfully requested.

Applicants have herein incorporated claim 19 into claim 1. As a result, since claim 19 was not included in Obviousness Rejection 2, withdrawal of this rejection is respectfully requested.

An early, favorable Office Action is earnestly solicited.

The Examiner is invited to contact the undersigned at the telephone number below if the undersigned can be of any assistance.

Respectfully submitted,

/Paul A. Fair, Reg. No. 35,866/

Paul A. Fair, Esq.

Reg. No. 35,866

Phone: (215) 299-6723

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Please send all correspondence to:

Patent Administrator

FMC Corporation

1735 Market Street

Philadelphia, PA 19103